OSTEOMED

510(k) Summary

AUG - 1 2008

NAME OF SPONSOR:

OsteoMed L.P
3885 Arapaho Road
Addison, Texas 75001

CONTACT PERSON:

Alma Relja
Regulatory Affairs Specialist
Phone (972)-677-4781
Fax: (972)-677-7448

Date Prepared: June 25, 2008

COMMON NAME: Metatarsal Resurfacing Implant System

CLASSIFICATION: Class II

DEVICE CODE: KWD

REGULATION #: 21 CFR 888.3730

TRADE NAME:
OsteoMed Metatarsal Resurfacing Implant System with Hydroxylapatite Coating

SUBSTANTIALLY EQUIVALENT DEVICE(S):
OsteoMed Metatarsal Resurfacing Implant System (K073065)

SUMMARY:

The OsteoMed Metatarsal Resurfacing Implant, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint.

The OsteoMed Metatarsal Resurfacing Implant is intended to be used with bone cement or press fit without bone cement.

The OsteoMed Metatarsal Resurfacing Implant is intended for single use only.

The OsteMed Metatarsal Resurfacing Implant is a one piece implant designed to replace the distal head of the metatarsal and provides a smooth articular surface for the adjacent phalangeal base. The implant is available in several sizes in direct proportion to the anatomic construct of the metatarsal head.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OsteoMed L.P.
% Ms. Alma Relja
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

AUG - 1 2008

Re: K081876
Trade/Device Name: OsteoMed Resurfacing Metatarsal Implant System with Hydroxylapatite Coating
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: June 30, 2008
Received: July 2, 2008

Dear Ms. Relja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081876

Device Name: OsteoMed Metatarsal Resurfacing Implant with Hydroxylapatite Coating

Indications for Use:

The OsteoMed Metatarsal Resurfacing Implant, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint.

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081876